JUL 2 5 2000

K001375

SUMMARY OF SAFETY AND EFFECTIVENESS

A. INFORMATION

1. SUBMITTER'S

Name:	BEST MANUFACTURING COMPANY
Address:	579 Edison Street Menlo, GA 30731 USA
Telephone Number:	706 862 2302
Contact Person:	David C. Young
Date Summary Prepared:	2000-04-27

2. NAME OF DEVICE

Trade or Proprietary Name:	Ultimate N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile (for protection against specified chemotherapy drugs)
Common or Usual Name	Non-Sterile Nitrile Powder-Free Patient Examination Glove
Classification Name:	Patient Examination Glove (for protection against specified chemotherapy drugs)

3. PREDICATE DEVICE — N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile K992170

IDENTIFICATION NAME, NUMBER

4. DESCRIPTION OF DEVICE

a. How the device functions:

Nitrile rubber films form an excellent barrier to body fluids and bloodborne pathogens. It also acts as an excellent chemical barrier.

b. Scientific concepts that form the basis for the device:

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing fine movement necessary for treatment. The absence of natural rubber latex in the

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product yields no latex protein allergens. The nitrile rubber has also been shown to prevent the breakthrough of the tested chemotherapy drugs when immersed for >8 hours.

c. Physical and performance characteristics such as design, materials, and physical properties:
Nitrile rubber is known to create a superior barrier to bloodborne pathogens, body fluids and chemicals

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASE OR CONDITIONS THAT THE DEVICE WILL ADDRESS
This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between the patient and examiner. Powder-free examination gloves are suitable in situations where powder is not desirable. Device used for protection against exposure to indicated chemotherapy drugs.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE
- The proposed device is identical to the predicate device, except the devices has a longer minimum lenght resulting in a thicker minimum thickness. The devise has undergone permeation testing to demonstrate performance with respect to specific chemotherapy drugs.
The proposed device has additional labeling: "Tested for use with: Cisplatin AQ; Mitoxantrone HCl; Doxorubincin HCl; Vincristine Sulfate; Ifosfamide; Fluorouracil; Carmustine; Etoposide; Dacarbazine; Methotrexate; Mitomycin.". Additional information included on the label or provided as an instruction sheet with each dispenser will be the statement "Gloves used for protection against chemotherapy drugs exposure must be selected specifically for the type of chemicals used.". Chemical resistance data and a material safety data sheet referral statement will also be provided.

B. IF SE DECISION BASED ON PERFORMANCE DATA:
1. DISCUSSION OF NON-CLINICAL TESTS

Specification	Proposed	Predicate
	Ultimate N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile (for protection against specified chemotherapy drugs)	N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile

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B. IF SE DECISION BASED ON PERFORMANCE DATA:

1. DISCUSSION OF NON-CLINICAL TESTS (Continued):

Performance Standards	ASTM	ASTM
Watertightness	ASTM	ASTM

2. DISCUSSION OF CLINICAL TESTS

Specification	Proposed	Predicate
Safety		
Rabbit Irritation	Passes	Passes
Guinea Pig Sensitization	Passes	Passes
Modified Draze Test (Human Study)	Passes	Passes

DESCRIPTION OF SUBJECTS
For the Modified Draze Test, 200 human subjects were used. The criteria for inclusion in the study was as discussed in the study, pages 6 and 7, paragraphs 3.11 and 3.12 (see Section M: Human and Animal Testing).

DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED
(with specific reference to adverse effects and complications)

This glove has been tested in accordance to ASTM F 739 Test method for Permeation of Chemicals Through Chemical Protective Clothing Under Conditions of Total Immersion, to demonstarte the level of protection provided by the glove against the specified chemotheraputic drugs. A report covering the permeation testing and the resulting level of protection offered by this glove is found in Section L.

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND Performance =/> PREDICATE PRODUCT

The Ultimate N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile (for protection against specified chemotherapy drugs) has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds

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accepted scores for the predicate product in both nonclinical tests and satisfies the requirements for a safe and effective "powder-free" medical glove. Further permeation test data shows the level of protection against the specified chemotherapy drugs.

Pursuant to 21 C.F.R. 807.87 (j), I David C. Young, Director, Regulatory Affairs and Quality Assurance, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director, Regulatory Affairs and Quality Assurance, for the Best Manufacturing Company, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

David C. Young, Director, Regulatory Affairs & Quality Assurance

2000-04-27
DATE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2000

David C. Young
Director, Regulatory Affairs & Quality Assurance
Best Manufacturing Company
Edison Street
Menlo, Georgia 30731-0008

Re: K001375
Trade Name: Ultimate N-Dex Powder Free Nitrile Examination Glove (Tested For Use With Chemotherapy Drugs)
Regulatory Class: I
Product Code: LZA
Dated: April 27, 2000
Received: May 1, 2000

Dear Mr. Young:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Devices Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: **Best Manufacturing Company**
510(k) Number (if known) *
Device Name: **Ultimate N-DEX Nitrile Medical Examination Glove, Powder-free, Non-Sterile** (Tested For Use With Chemotherapy Drugs)

The **Ultimate N-DEX Nitrile Powder-Free Medical Examination Glove** is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner. Device also provides protection against exposure to indicated chemotherapy durgs (21 CFR 880.6251).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K001375

Prescription Use_____ OR Over-The-Counter X
Per 21 CFR 801.109

* For a new submission, do NOT fill in the 510(k) number blank.